SOPP 8413 – Attachment A-

PMC Annual Report Review Form

For 601.70 Reportable Commitments

Δn	plication	Informa	ation
ΛP	piication	1111011110	ation

BLA/NDA	
Product	
Applicant	
Annual Report/PMC STN	
Annual Report Received Date	

Current Reviewers

Office	
RPM/Coordinator	
Reviewer	
Reviewer	
Reviewer	

Verification of the Reported Status and Status Explanation for Open Commitments

STN Generating the PMC	RMS-BLA Commitment #	Commitment Description	Reported on? (If any 601.70 PMCs are not reported on, the applicant must be contacted to amend the annual report to include all such PMCs.	Do you agree with the Applicant's reported status? (Yes/No)	Do you agree with the Applicant's reported status explanation? (Yes/No) Explain disagreements below	Was the corrected Status and/or Status explanation communicat ed to the Applicant?
1						
1						
1						
1						
1						
1						

STN Generating the PMC	RMS-BLA Commitment #	Commitment Description	Reported on? (If any 601.70 PMCs are not reported on, the applicant must be contacted to amend the annual report to include all such PMCs.	Do you agree with the Applicant's reported status? (Yes/No)	Do you agree with the Applicant's reported status explanation? (Yes/No) Explain disagreements below	Was the corrected Status and/or Status explanation communicat ed to the Applicant?
1						
1						

Review

For each FDAMA commitment where you do not agree with the applicant's reported status and/or status explanation, please address the following:

- Explain the disagreement.
- State concisely the correct status and/or status explanation that should be reflected in RMS-BLA and on the Web site.

Reviewer Signature	Date
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RETURN TO THE RPM WHEN COMPLETED